

REMARKS

The applicant respectfully requests reconsideration of claims 54-94 in view of the foregoing amendment, and consideration of new claims 95-105. These claims now will be discussed in the context of the matters raised in the present action.

A. Claim 54 is subject to an objection based on the term “access.” Pursuant to the amendment, claim 54 has been clarified by replacing the term with “axis.”

B. Claims 54 and 68-94 have been rejected under the judicially created doctrine of obviousness-type double patenting, based on claims 1-10, 14, and 23-37 of U.S. Patent No. 6,592,617. Similarly, claims 58 and 59 have been rejected for alleged obviousness-type double patenting, based on claims 1 and 2 of U.S. Patent No. 6,689,162.

In connection with both of these rejections, it is asserted in the present action that the conflicting claims are not patentably distinct from each other because the pending claims are broader in scope and drawn to the same embodiment.

These assertions are respectfully traversed. However, given the negligible impact of a terminal disclaimer on the term of the patent eventually issued on this application, the applicant is agreeable to filing a terminal disclaimer.

Accompanying this amendment is a terminal disclaimer, signed on behalf of the assignee of the present application, disclaiming any portion of the term of a patent issuing on this application that otherwise might extend beyond the full statutory term of U.S. Patent No. 6,592,617; and further disclaiming any portion of the term of a patent issuing on this application that otherwise might extend beyond the full statutory term of U.S. Patent No. 6,689,162. This application, the ‘617 patent and the ‘162 patent are commonly owned. Accordingly, it is submitted that the terminal disclaimer overcomes the obviousness-type double patenting rejections.

C. Claims 54-56, 60-69, 73-77, 80, and 82-94 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,697,969 (Schmitt, et al.).

The Schmitt patent discloses a vascular prosthesis formed with a braided tubular fabric having several braided layers. Each layer includes an interlocking yarn extending into another layer. Several embodiments also include a polyester monofilament interbraided with the yarns.

For example, Figures 3, 4, and 11 show prostheses in which Dacron polyester monofilaments (32, 42) are interbraided with Dacron polyester multifilament yarns and Maxon monofilament suture yarns. Schmitt teaches a process for fabricating these vascular prostheses in which the yarns and the monofilaments are braided together to form the tubular braided structure, and then the tubular braided structure is heated to thermally set the structure.

Claim 54 defines a three-dimensionally braided structure that includes both structural strands and textile strands. The textile strands are the more compliant. The structural strands have respective nominal shapes when in a relaxed state. Each structural strand is adapted to be altered to acquire a selected nominal shape different from an original nominal shape. Only the structural strands are so altered. In their selected nominal shapes, the structural strands form windings about a longitudinal axis with tubular profiles. The structural strands further are oriented within the braided structure to impart a tubular predetermined nominal shape corresponding to their tubular profiles. The textile strands tend to conform to the predetermined nominal shape imparted by the structural strands. This final feature, added by the present amendment, is intended to clarify the claim to further emphasize that the textile strands are more compliant.

Thus, claim 54 defines a prosthesis in which structural strands and textile strands are interbraided, and only the structural strands are altered to acquire a selected nominal shape different from an original nominal shape. In other words, the more compliant textile strands of the braided structure are not so altered.

The present application discloses two different approaches for achieving this result, even when the textile strands like the structural strands are adapted to be altered to acquire selected nominal shapes different from their original nominal shapes. In the first approach, the structural strands are thermally set to acquire their selected nominal shapes before they are interbraided with the textile strands. Unlike the “braid first, then heat set” approach of Schmitt, this allows the use of metallic structural strands, more generally structural strands having a heat-set temperature higher than the melting temperature of the textile strands.

In the second approach, the structural strands are resilient and ductile, and are altered into their selected nominal shapes by selective plastic deformation. Again, the structural strands are selectively shaped before they are interbraided with the textile strands.

In either case, it is readily apparent that: (1) the resulting braided structure includes both textile strands and structural strands; and (2) only the structural strands are altered to acquire selected nominal shapes.

As noted above, Schmitt teaches braiding the strands together first, then thermally setting the interbraided structure. The following excerpt from Example 2 in Schmitt is representative:

After braiding, the prosthesis was removed from the mandrel and placed over a 5 mm diameter mandrel and heat-set at 150° C. for 30 minutes. (Column 5, lines 44-47).

Schmitt does not explicitly state whether heat setting “the prosthesis” heat sets the monofilaments and the multifilament yarns; only the monofilaments; or only the yarns. However, the fact that the monofilaments and the multifilament yarns are formed of polyester suggests that both the monofilaments and the yarns are heat set. Alternatively, the polyester monofilaments and polyester multifilament yarns might differ from one another as to heat-set temperature. Given the need for greater strength in the monofilaments to structurally support the prosthesis, the monofilaments in this case are likely to have the higher heat-set temperature. Consequently, when the prosthesis is heated to a temperature between the heat-set temperatures of the monofilaments and the yarns, one would expect the yarns, not the monofilaments, to be thermally set.

In any event, regardless of which outcome (yarns and monofilaments heat set, just the yarns heat set, just the monofilaments heat set) is the most likely, the only outcome that would support the alleged anticipation of claim 54 - i.e., that just the monofilaments are heat set - is not inherent in Schmitt.

In short, Schmitt does not teach the claimed prosthesis, nor does it teach subject matter from which the claimed prosthesis would be the inherent result. Accordingly, Schmitt fails to anticipate the prosthesis defined in claim 54.

Claims 55, 56, 60-69, 73-77, 80, and 82 depend on claim 54 and are patentable for the reasons given in support of claim 54. Certain of these claims are patentable, further, as follows:

Claim 55, because Schmitt does not teach structural strands made of resilient and ductile material;

Claim 65, because Schmitt does not disclose drug eluting strands; and

Claim 68, because Schmitt does not disclose structural strands formed of metal.

Claim 83 defines a prosthesis similar to the prosthesis defined in claim 54 in that only the structural strands are altered, in this case thermally altered, to acquire the selected nominal shapes. In other words, the braided structure incorporates structural strands that are altered, interbraided with textile strands that are not.

Accordingly, the Schmitt patent fails to anticipate the prosthesis of claim 83, for the reasons given in support of claim 54.

Claims 84-94 depend on claim 83 and are patentable for the reasons given in support of claim 83. Certain claims are patentable, further, as follows:

Claim 84, because Schmitt does not teach that its monofilaments have a heat set temperature higher than a melting temperature of its multifilament yarns; and

Claim 90, because Schmitt does not teach the claimed structural materials.

D. Claim 65 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmitt in view of U.S. Patent No. 5,092,877 (Pinchuk).

Pinchuk discloses a radially expandable prosthesis, and notes that stents can be treated so that drugs can be eluted therefrom.

Claim 65 further defines the prosthesis of claim 54 in that the structural and textile strands are braided into first and second layers, and that a plurality of drug eluting strands are braided into the first layer.

Regardless of the extent to which Pinchuk is assumed to teach drug eluting fibers, the reference contains no teaching to provide the subject matter not taught by Schmitt as discussed above in connection with claim 54. Accordingly, claim 65 is patentable over the Schmitt/Pinchuk combination.

E. Claims 70-72 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmitt.

Claims 70-72 further define the prosthesis of claim 54 as to the size and composition of the multifilament yarns making up the textile strands.

It is asserted in the present action that such features would be obvious.

However, even if certain features relating to multifilament yarn size and composition are assumed to be obvious arguendo in view of Schmitt, a prosthesis in which structural strands and textile strands are interbraided, and in which only the structural strands are altered to acquire selected nominal shapes, is not obvious in view of Schmitt. As noted above, there is no explicit teaching of such prosthesis in Schmitt, and no teaching in Schmitt from which such prosthesis would be the inherent result.

F. Claims 78 and 79 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmitt in view of U.S. Patent No. 5,423,849 (Engelson, et al.).

The Engelson patent discloses a tubular braid woven from radiopaque fibers, and partially from radiolucent fibers, if desired. Claims 78 and 79 further define the prosthesis of claim 54 to include at least one radiopaque strand.

Regardless of the extent to which Engelson is deemed to teach radiopaque strands, this patent contains no disclosure of the subject matter not taught by Schmitt as discussed above in connection with claim 54. Accordingly, claims 78 and 79 are patentable over the Schmitt/Engelson combination.

G. Claims 58 and 59 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmitt in view of U.S. Patent No. 5,061,275 (Wallsten, et al.).

Claims 58 and 59 further define the prosthesis of claim 54 to add an elongate and flexible catheter, with the prosthesis being mounted on the catheter, along with a means for releasably maintaining the prosthesis at the catheter distal end.

Regardless of its teachings relating to a catheter, Wallsten does not include any disclosure that provides the subject matter not taught by Schmitt as discussed above in connection with claim 54. Accordingly, claims 58 and 59 are patentable over the Schmitt/Wallsten combination.

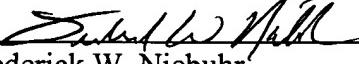
H. The indication that claim 57 incorporates allowable subject matter is noted and appreciated. New claim 95 incorporates the features of claims 54, 56 and 57, and thus is considered equivalent to claim 57 rewritten in independent form. Claims 96-105 depend on claim 95.

To summarize, it is submitted that claims 54-94, along with new claims 95-105, incorporate subject matter patentable over the prior art of record, and define that subject matter with clarity and precision. An early and favorable action allowing claims 54-105 is earnestly requested.

Respectfully submitted,

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Date: January 18, 2005

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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment and accompanying Terminal Disclaimer in Application Serial No. 10/619,888 are being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Date of Deposit: January 18, 2005


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